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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/570,735 | 12/06/2006 | Shrirang Netke | 11957/47204 | 7205 |

7590 02/01/2010
Ali Kamarei, Esq.
280 Colorado Avenue
Palo Alto, CA 94301

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| EXAMINER |
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CHOI, FRANK I

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| ART UNIT | PAPER NUMBER |
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1616

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| MAIL DATE | DELIVERY MODE |
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02/01/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/570,735 | Applicant(s) NETKE ET AL. | |
| | Examiner FRANK I. CHOI | Art Unit 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/6/2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>3/6/2006</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Drawings

The drawings are objected to because Figs. 1-4 (3/6/2006) are unclear. The images of the bones are not sufficiently distinct from the background (the examiner suggests outline drawings or submission of photos provided that the photos are clear when photocopied). The background of Fig. 3 obscures the data points. The shading is not distinct enough in figure 4. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

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As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

The Brief Description of the Drawings section needs to be move from the last page to area indicated above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 202 07 569 U1 in view of Rosenberg et al. (US Pat. 6,579,544), Brown et al. (US Pat. 6,528,042), Fini et al., Ibsen et al., Dollwet et al. and Dodds et al..

DE 202 07 569 U1 discloses a dietary supplement containing lysine, proline, Vitamin C, copper, Vitamin B6 and Vitamins A, D3, B1, B2, niacin, folic acid, B12, biotin, pantothenic acid and calcium, phosphorous, magnesium, zinc, selenium, manganese, chromium, molybdenum, potassium, hesperidin, arginine, cystein, myo-inositol, carnitine, ubiquinone and bioflavonoids (See entire document).

Rosenberg et al. discloses that vitamin C is essential for the healing of bone fractures and that such fracture heal slowly in a patient deficient in vitamin C (Column 9, lines 32-54). It is disclosed that bioflavonoids promote vitamin C activity and include hesperidin which is found in the rinds of oranges and lemons and proanthocyanidins (Column 18, lines 11-26). It is disclosed that Coenzyme Q10 (ubiquinone) is found in every cell in the body and serves to prevent the cellular damage the results from normal metabolic processes and that deficiencies can occur during stress (Column 21, lines 47-68).

Brown et al. disclose that the combination of flavonoids or flavonoids and synergists, where the flavonoid can be hesperidin or pycnogenol and the synergist can also be a flavonoid, carnitine, lysine, arginine or tocopherols and that pycnogenol and hesperidin are used for ameliorating injuries (Column 19, lines 20-68, Column 20, Column 21, lines 1-4).

Fini et al. disclose that the rationale for using lysine in fractures is that lysine stimulates intestinal calcium absorption and renal conservation and cross-linking process of bone collagen (page 214). It is disclosed that L-proline acts as a substrate for collagen synthesis (page 214).

Ibsen et al. disclose that administered proline is used during bone healing (Pages 803, 804).

Dollwet et al. disclose that copper supplementation increases the rate of bone healing (Abstract).

Dodds et al. disclose that delayed fracture healing was observed in vitamin B6 deficient rate (Abstract).

DE 202 07 569 U1 discloses a dietary supplement containing lysine, proline, Vitamin C, copper, Vitamin B6 and Vitamins A, D3, B1, B2, niacin, folic acid, B12, biotin, pantothenic acid and calcium, phosphorous, magnesium, zinc, selenium, manganese, chromium, molybdenum, potassium, hesperidin, arginine, cysteine, myo-inositol, carnitine, ubiquinone and bioflavonoids. The difference between DE 202 07 569 U1 and the claimed invention is that DE 202 07 569 U1 does not expressly disclose a method for facilitating bone healing in a mammal by administering the combination of lysine, proline, ascorbic acid, copper and vitamin B6. However, the prior art amply suggests the same as the prior art discloses the same as a nutritional supplement (DE 202 07 569 U1), that vitamin C is necessary for healing bone fractures (Rosenberg et al.), lysine increases calcium in the body and stimulates cross-linking of collagen (Fini et al.), proline is used as a substrate for collagen synthesis and in bone healing (Ibsen et al.; Fini et al.), that vitamin B6 deficiency leads to delayed fracture healing (Dodds et al.) and that pycnogenol is suitable for use in compositions for ameliorating injuries (Brown et al.). As such, one of ordinary skill in the art would have been motivated to administer the composition disclosed in DE 202 07 569 U1 wherein the flavonoids include pycnogenol with the expectation that the composition would be effective in increasing the rate of bone healing.

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Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Wednesday and Thursday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
June 30, 2009

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616